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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,920	02/20/2002	Motasim Sirhan	020460-000230US	1180

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,920

Applicant(s)

SIRHAN ET AL.

Examiner

Sarah K. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,74,76,79-85,91,97-101 and 107 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,74,76,79-85,91,97-101 and 107 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,91,97-101, and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amendments to claims 1 and 2 have rendered all claims indefinite. The first balloon structure has a shaft and a passage that is slidably receivable over a catheter body. The passage of the balloon structure in the elected species of Figure 5A is not “*receivable over the shaft*”, because the shaft is connected to the proximal end of the balloon structure. Page 14, lines 14-19 of applicant’s specification reads:

The shaft further includes a sleeve portion 38 at the shaft distal section, having an axial passage 41 there through which is configured to be slidably disposed over an elongate body such as elongate body 12 shown in FIG. 2A or a guidewire. For example, the passage is configured to be receivable over the elongate body or slidably receive the elongate body. At least a portion of the sleeve forms the inflation lumen 29 extending within the inflatable member.

Since the shaft is connected to the sleeve and balloon, it is not possible for the passage of the balloon structure “receive” its own shaft. As underlined above, the elongate body (12) is the catheter body, not the balloon structure shaft (26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1,2,11,12,16-18,22,23,26-28,35,46-49,69,70,73,76,79-85,91,97-101,107,132-136,140-142,144, and147-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,655,746 to Daniels et al. in view of US Patent No. 5,135,535 to Kramer.

As best illustrated in cross section in Figure 3, Daniels discloses a balloon catheter that includes:

- a. A catheter body (68) with a guide wire (74) positioned in a guide wire lumen (70) and;
- b. A first balloon structure shaft (16) that has a passage (18) that receives the catheter body (68).

Daniels fails to form the balloon structure shaft (16) to have an axial groove in communication with the passage (18). Kramer discloses another balloon catheter that includes a first balloon structure shaft (11) that has a passage (14) that receives a guide wire (29). Kramer teaches that the shaft (11) should include an axial slit (23,24), or groove, along the length of the shaft proximal to the balloon. The groove (23,24) allows the balloon structure shaft (11,13) to be removed from the guide wire (29) while the guide wire (29) remains stationary in the body lumen. A replacement catheter may then be subsequently delivered over the guide wire (see column 6, lines

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22-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an axial groove on the shaft of Daniels that communicates with the passage, as Kramer teaches that this allows the balloon structure shaft to be removed from the inner catheter and guide wire. This would allow a replacement catheter to be delivered over the inner catheter and guide wire so that multiple functions could be performed within the body lumen.

The catheter body (68) of Daniels has a circular shape and a lumen (70). As shown in Figure 5, an atraumatic tip (76) is positioned at the distal end of the catheter (68) (column 4, lines 55-57). Regarding claim 17, the distal end (16b) of the balloon structure (16) is distally tapered and has multiple lumens (see Figure 4). The catheter body (68) is formed from a polyethylene, a polymer (column 4, line 50). Regarding claims 22 and 26, the balloon structure includes a shaft (16) with an inflatable balloon (30) on the distal end and an inflation lumen (24)(column 3, lines 39-41). The passage (18) of the balloon structure (16) extends both proximally and distally of the balloon (30). Daniels explains that the balloon structure includes a sleeve (32) with an inflatable portion (30)(column 3, lines 50-60). Daniels gives the dimensions of the catheter body. The diameter of the catheter is 20-50 mils (column 4, line 37), which when converted to French (F), falls within the claimed range. The length is 40-140 cm (column 3, line 33). Since the groove extends over a majority of the length of the catheter shaft, it would also have a length within the claimed range of 10-150 cm. Regarding claims 82-85 and 150-153 Kramer states that it is well known in the art of balloon catheters that guide wire diameters range from 0.008 to 0.035 inches (column 7, lines 28-30), or 0.02 – 0.09 cm. Therefore, it would have been obvious to form the passage and groove to accommodate a guide wire that has a size within this range.

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3. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, and in further view of US Patent No. 5,830,227 to Fischell et al.

The modified Daniels device includes all the limitations of Fischell, except for a tapered distal end on the catheter. Fischell discloses another balloon catheter with a guide wire. Fischell teaches that the distal tip of the catheter body should be distally tapered between 1 and 5 cm so that the catheter can follow the guide wire more easily (column 1, line 42 and column 4, line 65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a tapered distal tip on the catheter of the modified Daniels device, as Fischell explains that this helps the catheter to follow the guide wire through tortuous paths.

4. Claims 20,21, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, and in further view of US Patent No. 5,195,978 to Schiffer.

The modified Daniels device includes all the limitations of claims 21 and 71, except for forming the catheter as multiple bodies connected together. Schiffer teaches that a catheter body can have another tubular member, such as a hypotube, coupled to the proximal end for stiffening purposes (column 9, lines 5-7). Hypotubes are commonly formed of stainless steel and nickel-titanium alloys. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the catheter of the modified Daniels device as multiple connected bodies, as Schiffer teaches that this structure can add strength to the catheter body.

5. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, as applied to claims 1 and 2 above, and further in view of US Patent No. 5,395,335 to Jang.

The modified Daniels device fails to form the groove as multiple intermittent grooves, but Jang teaches that the groove can be formed as multiple intermittent grooves, or perforations. It would have been obvious to substitute the continuous groove with a perforated groove. This is an obvious modification, since both types of grooves perform the same function.

Response to Arguments

6. Applicant's arguments filed 9/8/05 have been fully considered but they are not persuasive. Applicant argues that the amendments more clearly claim the present invention and the examiner has "mischaracterized" the passage of the balloon structure. The amendments have raised new 112 issues – see above for clarification. Examiner even notified applicant of possible 112 issues due to amendments in an Advisory Action dated 6/23/05. Therefore, the prior rejection has been maintained and arguments based on this language are considered moot.

Applicant argues that none of the references cited teach or suggest an axial groove that extends along a passageway in a balloon catheter shaft. Clearly, the references do contain teachings pertaining to an axial groove along a balloon catheter shaft that allows an inner elongate member to be removably received in a passageway. The claim limitations are significantly broad enough to encompass the groove structures disclosed in the prior art, especially due to the fact that the invention is not clearly claimed. Many of the references cited, such as Kramer and Schiffer, include

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teachings pertaining to the axial groove. The groove allows the balloon catheter to be removed from the inner member disposed in the passage. Since motivation is found in the prior art, the 103 are considered to be proper.

Conclusion

7. This is a continued examination of Application No. 10/080,920. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
10/22/05

SKW
Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER